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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/027,792      | 12/20/2001  | John R. Adler        | 1010497-991130      | 2683             |

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06/15/2005

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EXAMINER

MANTIS MERCADER, ELENI M

ART UNIT PAPER NUMBER

3737

DATE MAILED: 06/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/027,792

Applicant(s)

ADLER, JOHN R.

Examiner

Eleni Mantis Mercader

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 March 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                                                        |                                                                                         |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

## DETAILED ACTION

### *Response to Arguments*

1. Applicant's arguments filed on 03/23/2005 have been fully considered but they are not persuasive. The limitations of "non-void" target region constitute new matter. Therefore a 112 1<sup>st</sup> is now instituted. The art rejections reflect the "non-void" limitation. With respect to claim 17, means plus function was interpreted within the scope of 112 6<sup>th</sup> and the rejection addresses the apparatus as that means and equivalents thereof.

### *Claim Rejections - 35 USC § 101*

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-29 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims inferentially claim the human body. Any limitations referring to attaching, or connecting or inserting into the tissue should be amended with functional language such as "adapted" to avoid inferentially claiming the human body. For example, "securing the body portion within the tissue" should be changed to --adapted for securing the body portion within the tissue--, "means for anchoring the body portion within tissue" should be amended to --means adapted for anchoring the body portion within tissue--, "securing the body portion within the tissue" should be amended to --adapted for securing the body portion within the tissue--.

### *Claim Rejections - 35 USC § 112*

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The newly added limitations of "non-void" constitute new matter as this limitation was not originally disclosed.

*Claim Rejections - 35 USC § 103*

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-3, 7-19 and 23-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sirimanne et al.'904 in view of Foester et al.'304.

Sirimanne et al.'904 teaches a fiducial apparatus to be inserted into a target region, comprising:

a body portion made of a material that is visible using electromagnetic radiation, including radioopaque or echogenic (col. 2, lines 54-60); and one or more anchoring devices connected to the body portion (col. 5, lines 4-11), each anchoring device having an unanchored position and an anchored position (col. 13, lines 54-62), the unanchored position permitting the

body portion to move within the target region and the anchored position anchoring the fiducial apparatus into the target region (col. 13, lines 63-67 and col. 14, lines 1-6).

Sirimanne et al.'904 teach the body portion comprising a memory metal member that bends in response to an appropriate signal to anchor itself into the target region (see col. 13, lines 57-62).

Sirimanne et al.'904 teach the target region comprising a target region within a human body such as a tumor (see col. 1, lines 20-58).

Sirimanne et al.'904 teach the insertion further comprising injecting the fiducial into the target region using a needle (see device 400 in Figures 4A-4C).

Sirimanne et al.'904 teach wherein the anchor member is an elongated rectangular shaped member that embeds into the target region (see Figure 1C).

Sirimanne et al.'904 do not explicitly teach an anchoring device further comprising an anchor member and an elastic member connected to the anchor member that urges the anchor member into the anchored position or application of the anchoring device in non-void tissue.

In the same field of endeavor, Foester et al.'304 teach a spring structure (or an elastic member) connected to the anchor member that urges the anchor member into the anchored position (see paragraph 0019) wherein the anchor member can thereby be attached to non-void tissue.

It would have been obvious to one skilled in the art at the time that the invention was made to have modified Sirimanne et al.'904 and incorporated the teachings of Foester et al.'304 of incorporating a spring structure as that enhances the implantation of the marker (as explained by Foester et al.'304 in paragraph 0019) in tissue such as non-void tissue.

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Foester et al.'304 teach an anchor member comprising a spike that embeds itself into the target region or a pyramidal shaped member (see Figures 17, showing multiple spikes or multiple pyramidal members).

It would have been obvious to one skilled in the art at the time that the invention was made to have moved one or more anchor devices into an anchored position in order to embed the one or more anchor devices into the target region, depending on the size of the target of interest, requiring more marking identification, as this is a well known practice to those skilled in the art.

7. Claims 4-6 and 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sirimanne et al.'904 in view of Foester et al.'304 and further in view of Flomenblit et al.'641.

Sirimanne et al.'904 do not explicitly teach that an appropriate signal further comprises an electric field or a predetermined temperature.

In the same field of endeavor, Flomenblit et al.'641 teach the use of an appropriate signal further comprising a predetermined temperature to insert a coiled structure into the area of interest (see col. 2, lines 61-67 and col. 3, lines 1-64). Note that an electric field is required to change the temperature since an electronic apparatus is used.

It would have been obvious to one skilled in the art at the time that the invention was made to have modified Sirimanne et al.'904 and incorporated the teachings of Flomenblit et al.'641 in order to introduce the coiled marker (such as the one indicated in Figure 5D of Sirimanne et al.'904) into the area of interest.

Sirimanne et al.'904 teach the memory metal further comprising nitinol (see col. 13, lines 54-62).

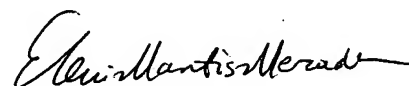
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*Conclusion*

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eleni Mantis Mercader whose telephone number is (571) 272-4740. The examiner can normally be reached on Mon. - Fri., 8:00 a.m.-6:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Eleni Mantis Mercader  
Primary Examiner  
Art Unit 3737

EMM